Chapter 6

RISK

This chapter presents module descriptions for the risk-related component of a CTSA, including the following analytical modules:

- Workplace Practices & Source Release Assessment.
- Exposure Assessment.
- Risk Characterization.

Data from the Workplace Practices & Source Release Assessment module combine with data from the Chemical Properties and Environmental Fate Summary modules to provide the foundation for the Exposure Assessment module. Data from the Exposure Assessment module then combine with data from the Human Health Hazards Summary and Environmental Hazards Summary modules to characterize risks in the Risk Characterization module.

Data from all three of these modules flow into the final trade-off evaluations presented in Chapter 10. For example, the source and quantities of environmental releases from the Workplace Practices & Source Release Assessment module are qualitatively evaluated in the Social Benefits/Costs Assessment module for the effects of pollution on health, recreation, productivity, and other social welfare issues. The social benefits of reduced risk are considered more quantitatively using data from the Risk Characterization module.

The Exposure Assessment module provides the amounts of environmental releases that were not quantified in the Workplace Practices & Source Release Assessment module (e.g., solvent emissions from open containers that were modeled during the Exposure Assessment) to the Risk, Competitiveness & Conservation Data Summary module for evaluation with the other release data. It also provides an evaluation of the potential for exposure (e.g., high, medium, or low) by different pathways (e.g., ingestion, inhalation, dermal) to the Risk, Competitiveness & Conservation Data Summary module. Past CTSAs have used exposure levels as an indicator of the potential for risk when health and environmental hazard data are not available.

The Risk Characterization module provides human health and ecological risk data to the Risk, Competitiveness & Conservation Data Summary module for evaluation in the Social Benefits/Costs Assessment and Decision Information Summary modules. The former module considers the social benefits of reduced risk and folds these benefits into an overall evaluation of the net benefits (or costs) to society of a substitute. The Decision Information Summary module presents the risk data directly in the final trade-off evaluations where individual decision-makers consider all of the issues to choose the alternative that best fits their particular situation.

WORKPLACE PRACTICES & SOURCE RELEASE ASSESSMENT

OVERVIEW: The survey of workplace practices and source release assessment is the process of: (1) identifying and collecting data on workplace activities that may contribute to worker exposure; and (2) identifying the sources and amounts of environmental releases. The collected data are analyzed to determine the sources, nature, and quantity of both on-site releases (e.g., chemicals released to the sewer, evaporative, or fugitive emissions from the process, etc.) and off-site transfers (e.g., discharges to publicly owned treatment works).

GOALS:

- Collect workplace practices data through discussions with industry experts, review of existing information, the performance demonstration project, or the dissemination of a questionnaire to industry.
- Create a profile of a typical or model facility which can be used as the model for source release and exposure assessment calculations.
- Perform a source release assessment on the model facility to identify and characterize both on-site and off-site chemical releases and transfers.
- Provide data needed for the Exposure Assessment module which estimates possible exposure concentrations to human health and the environment.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- In-depth knowledge of the process under review, including waste streams and their point sources.
- Understanding of the concepts of material balances.
- Knowledge of the workplace activities associated with the operation of the process.
- Experience with exposure assessment guidance and methodology.
- Understanding of chemical fate, transport modeling and exposure modeling.
- Knowledge of chemistry or environmental science.
- Knowledge of surveying techniques and methodologies if a survey is utilized.

Within a business or DfE project team, the people who might supply these skills include a process engineer, a process operator or specialist, a statistician, an industrial hygienist, an environmental engineer, and a chemist or environmental scientist. Vendors of equipment or chemicals used in the process may also be a good resource.

DEFINITION OF TERMS:

Basis: The reference point chosen for the calculations made in any particular problem.

Material Balance: An accounting of the flow of material in and out of a system, derived from the generalized law that the mass of a material is conserved throughout a process. A material balance can be used to identify the sources and quantities of chemical released to the environment.

Mole: The weight of a substance, in kilograms, equal to that substance's molecular weight in atomic mass units.

Periodic Table: A list of elements in order of increasing atomic number, arranged in tabular form such that elements having similar properties appear in vertical columns.

Stoichiometry: The quantitative relationship between constituents in a chemical substance or reaction.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for collecting workplace practices data and conducting a source release assessment. Further methodology details for Steps 2, 3, 5, and 12 follow this section. Two examples of workplace practices questionnaires can be found in Appendix A.

Survey of Workplace Practices

Step 1: Obtain the unit operations and process flow diagram from the Chemistry of Use & Process Description module. The process flow diagram and unit operations provide the framework from which the workplace practices questionnaire can be generated.

Step 2: Identify the data needed to perform both the source release and exposure assessments. Information regarding industry pollution prevention practices should also be collected.

Step 3: Create a workplace practices questionnaire to obtain the information identified in Step 2 for this and subsequent modules. Existing information, such as industry literature, published studies and industry or scientific databases, should be checked and data used when applicable, to prevent the survey from becoming unduly long.

Step 4: If time and resources permit, conduct a test-run of the questionnaire by either distributing it to a small group of test facilities, or by performing site visits at selected facilities to assist them with the completion of the questionnaire. The goals of the test-run are to:

- Identify problems that may exist with the questionnaire (i.e., questions that are unclear, etc.).
- Verify that the data collected from the survey are reasonably representative and complete and that relevant data are not excluded from the results (i.e., all pertinent waste streams are included in the questionnaire, workplace practices that may contribute to worker exposure are represented, etc.).
- If site visits are performed, collect verified data that can be used as a guideline for identifying errant questionnaire data that may be collected during the survey.

Step 5: Collect industry data using the workplace practices questionnaire from the appropriate source(s). Typical sources of data include industry experts, performance demonstration sites, and/or individual industry facilities. The methods used to collect the data depend mostly on the source and include:

- Completing the questionnaire through discussions with a group of industry experts.
- Using the questionnaire as an observer data sheet to be completed during the performance demonstration (see the Performance Assessment module for more information on this process).
- Disseminating the questionnaire to a representative sample of industry facilities.

Step 6: Tabulate the data, preferably in a computer data base, so that it may be readily compared and analyzed. Data to be tabulated may include questionnaire responses, performance demonstration results, and any established data found to be relevant.

Step 7: Inspect the tabulated data for reasonableness and consistency using professional judgment. Collected data that appear unreasonable (i.e., outlying data that are inconsistent with the majority of the data) should be verified with the facility or person responsible for reporting the data point. Data generated from site visits performed in Step 4 may be used as a guide for evaluating the survey data.

Step 8: Provide a list of chemical names collected from the questionnaire data to the Chemical Properties module for comparison against the chemical substitutes list. If additional chemical substitutes are identified from the questionnaire results, they should be included in the entire CTSA process (e.g., collect chemical properties, hazard data, etc.).

Step 9: Create a profile of an average (model) facility from the tabulated data in Step 6. This is done by computing the average or other representative value of the appropriate survey data collected during the survey (i.e., number of workers employed, number of shifts operated, amount of chemical used, amount of chemical released to air, etc.). The profile will be used as the model facility for source release and exposure assessment calculations.

Source Release Assessment

Step 10: Using the data from the model facility, the process flow diagram, and the results of the site visits, identify the sources of chemical releases to the environment. The sources of some of the releases will be clearly identified in the questionnaire while others, such as open containers of volatile chemicals that result in air emissions, will have to be modeled using other data, such as chemical properties data from the Chemical Properties module, together with the workplace practices data. In a CTSA, the modeling of chemical releases or transfers that cannot be explicitly estimated from the survey data (i.e., volatization of volatile organic compounds [VOCs] from open containers, etc.) is usually done in the Exposure Assessment module.

Step 11: Characterize each of the chemical releases identified in Step 10 by determining the following attributes:

- Location of the release; on-site (i.e., fugitive or evaporative process releases to air, stack emissions, etc.) or off-site (i.e., air releases from contaminated rags that have been sent to a cleaning service, etc.).
- Media to which the release takes place (i.e., air, water, or land).
- Quantity of the release. (In some cases, such as evaporative losses of VOCs from open containers, the quantity of release will need to be estimated using mathematical models. See the Exposure Assessment module for information on models used by EPA.)
- Composition of the release (e.g., weight or volume percent), if known or reported.

Peer-Review and Data Transfer

Step 12: Verify the accuracy and consistency of the source release and exposure assessment profile created for the model facility by using any or all of the following methods:

- Perform a physical examination on one or more facilities with similar characteristics to the model facility.
- Have knowledgeable industry representatives review the profiles.

- Perform data quality checks such as checking that the reported value for the amount of chemical disposed does not exceed the amount of chemical purchased.
- Perform material balances on the model facility and check the model for reasonableness.

Step 13: Submit the survey and source release results for peer-review by industry experts. Clearly state all assumptions used in calculating the releases, as well as any sources of uncertainty.

Step 14: Provide source release and workplace practices data collected by the questionnaire to the Exposure Assessment and Pollution Prevention Opportunities Assessment modules; source release data to the Control Technologies Assessment module; chemical handling data and process operating practices to the Process Safety Assessment module; and source release data to the Risk, Competitiveness & Conservation Data Summary module.

METHODOLOGY DETAILS: This section presents the methodology details for completing Steps 2, 3, 5, and 12. If necessary, additional information on conducting a source release assessment can be found in the published guidance.

Details: Step 2, Identifying Data Requirements

An important step in the performance of both the source release and exposure assessments is the identification of the data that must be collected. Data types that are typically collected for use in this or other CTSA modules include, but are not limited to, the following:

<u>Facility and Employee Information</u>

- Total population of workers in the industry.
- Number of workers at the facility.
- Number of workers at the facility who are potentially exposed to the chemicals in the use cluster.
- Number of operating days per year.
- Number of shifts run per day.
- Number of hours per shift.
- Number of hours of worker exposure to use cluster chemicals per shift.
- Dimensions of the operating area in which chemical exposure may occur.

<u>Worker Exposure Information</u>

- Name of chemical.
- Concentration of chemical.
- Operations/activities leading to potential chemical exposure.

- Duration of potential chemical exposure.
- Frequency of potential chemical exposure.
- Personal protective equipment used.

Source Release Information

- Amount of chemical purchased per year.
- Amount of chemical used per day.
- Total chemical releases by facility per year.
- Location of release (on-site or off-site).
- Media of chemical release.
- Amount of chemical releases per site per day.
- Frequency of chemical releases.
- Duration of chemical releases.

Other Information

- Pretreatment standards and discharge permits.
- Types of in-process engineering controls used to reduce exposures.
- Types of end-of-pipe control technologies used to reduce releases and exposures.
- Types of pollution prevention practices used to reduce or prevent releases.
- Types of recycling used in waste streams or elsewhere to mitigate releases.

Details: Step 3, Creating a Workplace Practices Questionnaire

The workplace practices questionnaire is the primary tool in the CTSA process for gathering data from industry. Because the information to be collected is often case-specific, the ideal questionnaire is tailored to the selected industry, and it results from the collaborative efforts of individuals possessing the people skills listed in this module.

The required exposure and source release data may be obtained directly from the questionnaire, or indirectly through calculations using the questionnaire results, together with other information. Data should be collected and presented on a per unit production basis, or some other basis that allows a comparative evaluation of the baseline and alternatives. The workplace practices questionnaire should not be unduly lengthy, as this will influence the quality and quantity of the responses that will be received.

Details: Step 5, Disseminating the Workplace Practices Questionnaire to Industry

Surveys should be disseminated to facilities of various sizes and production levels in a manner that will ensure the confidentiality of the facilities responding. Trade associations can fulfill this role by providing a list of target facilities to participate in the survey, and by acting as an intermediate, assuring the confidentiality of those facilities that participate. Trade associations have been responsible for disseminating the questionnaires for all of the previously performed CTSAs.

Details: Step 12, Verifying Accuracy and Consistency: Material Balance Principles

A material balance is an accounting of the flows of a material into and out of a system. Performing a material balance involves the following steps:

(1) Define a system boundary around which the material balance will be calculated. The boundary of the system for the material balance can be chosen as the entire process or any portion of the process where material streams enter or leave the system. Typically, for this type of application, the entire process shown in the process flow diagram created in the Chemistry of Use & Process Description module is selected.

(2) Develop a set of material balance equations that include terms for all of the streams entering or leaving the system boundary. A material balance can be performed using a:

- Material or substance (e.g., lubricating oil, plastic pellets, etc.).
- Chemical compound (e.g., water [H_2O], hydrochloric acid [HCl], natural gas [CH_4], etc.).
- Individual chemical element (e.g., Hydrogen [H], Carbon [C], Sodium [Na], etc.).

The material balance equation states that the inputs of the material must equal the outputs of the material plus any accumulation. This condition holds true as long as there is not a chemical reaction taking place.

(3) Enter quantities for known input and output streams into the set of material balance equations. Stream data can come directly from questionnaire data that have been collected or from individual company records if the questionnaire data on a stream are inconclusive. Input stream data can be typically obtained from purchase or inventory information. Output stream data can be obtained from reported waste stream information or calculated from chemical properties together with chemical use data.

(4) Mathematically solve the set of equations for any unknown or unquantified terms that remain. Only one unknown term for each material balance equation can be quantified. Therefore, there must be at least as many different material balance equations as there are unknown streams in order to solve the equation set. If there are more unknown terms than equations, and the system boundary cannot be redrawn to correct the situation, then performing a material balance is not possible and the unknown release will have to be modeled. In cases where the equation cannot be made to balance because of inaccuracies in data, then the releases, again, will have to be modelled.

For cases in which a chemical reaction occurs within the system, a material balance must consider the rate of consumption or production of the chemical constituents (see combustion example below). The balanced chemical equation is used to determine the limiting reactant of the chemical reaction. The limiting reactant is the reactant that is consumed entirely as the chemical reaction occurs. Through the use of a properly balanced chemical equation and molar ratios, the unknown reactant and product streams can be quantified. For additional assistance with applications involving chemical reactions consult a chemical engineering text (see Published Guidance section).

Shown below are two examples of material balance equations. The first is an example of a situation where a chemical reaction is not present in the process. Finally, a typical combustion problem is used as an example of a situation involving a chemical reaction within the system boundary.

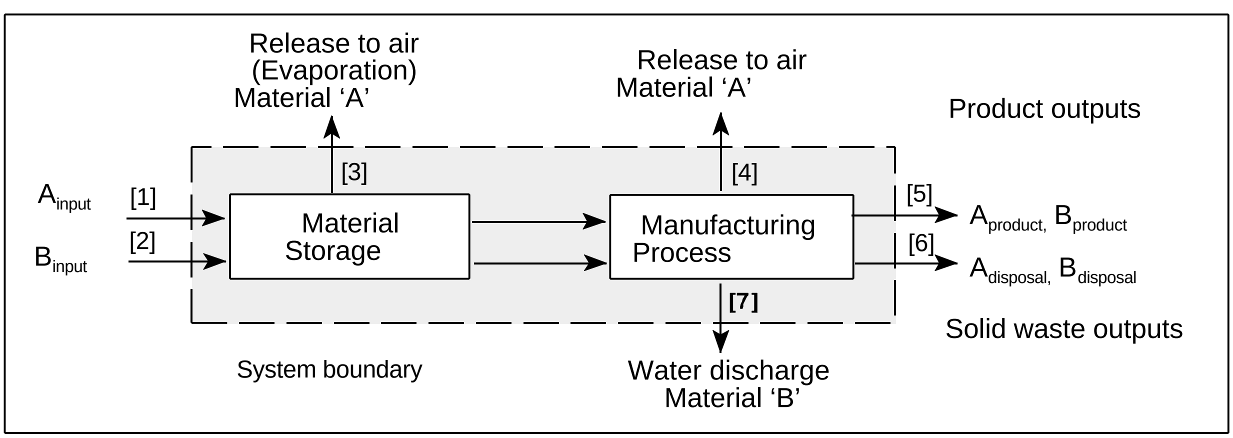
Example, Material Balance Without a Chemical Reaction Present

Figure 6-1 is an example of a material storage and component manufacturing process. The process is being run at steady-state so there is no accumulation of material within the system boundary. No chemical reaction occurs in the process.

Material Balance for Material 'A'
Mass In = Mass Out - Mass Accumulation
Mass In = Mass A_{Input} [1]
Mass Out = Mass A_{evap} [3]+ Mass A_{air} [4]+ Mass A_{prod} [5]+ Mass A_{disp} [6]
Mass A Accumulation = 0

Material Balance for Material 'B'
Mass In = Mass Out - Mass Accumulation
Mass In = Mass B_{Input} [2]
Mass Out = Mass B_{prod} [5] + Mass B_{disp} [6] + Mass B_{water} [7]
Mass B Accumulation = 0

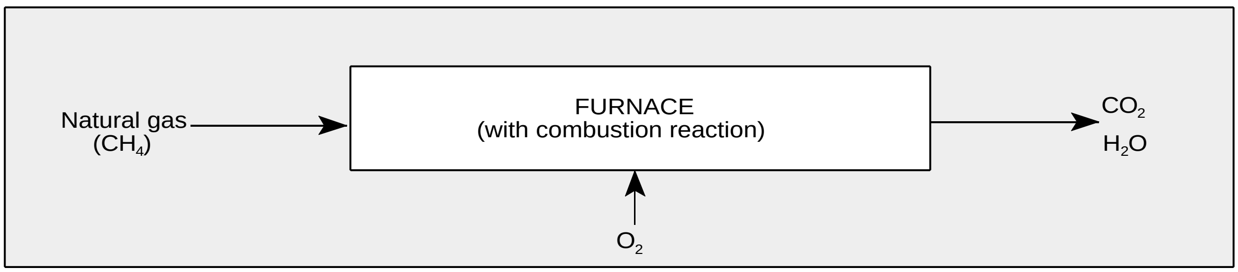
FIGURE 6-1: FLOW DIAGRAM OF MANUFACTURING PROCESS WITHOUT A CHEMICAL REACTION



Example, Chemical Reaction Present Within the System Boundary

In a material balance in which a chemical reaction is involved, the moles of a species (chemical compound) and the total moles of the reaction are not conserved. The mass balance must be made around the total mass and the mass or moles of each atomic species. In the example below, a total mass balance, and a carbon, hydrogen, and oxygen balance can be written. Figure 6-2 is an example of a furnace where the combustion of natural gas represents the reaction. The combustion of natural gas (CH_4) takes place in the presence of excess oxygen (O_2) which is typically supplied by air. Therefore, natural gas represents the limiting reactant and will be the basis for all calculations.

FIGURE 6-2: NATURAL GAS FURNACE PROCESS DIAGRAM



The combustion process is described by the following balanced chemical reaction:

Balanced Chemical Reaction: $CH_4 + 2\ O_2 \rightarrow CO_2 + 2\ H_2O$

This equation shows that for every one mole of CH_4 that reacts with two moles of O_2, one mole of carbon dioxide (CO_2) and two moles of water (H_2O) are produced. From this information, and using the basis of 100 kilograms (kg) per hour of CH_4, the following data can be calculated:

(1) Calculate the moles of natural gas (CH_4) consumed using the molecular weight for CH_4. The molecular weight can be found by consulting a periodic table and totaling the individual atomic weights of one carbon atom (C = 12) and four hydrogen atoms (H = 1).

Molecular weight of CH_4: 12 + 4 (1) = 16

Moles of CH_4: 100 kg ÷ 16 kg/mol = **6.25 moles of CH_4**

(2) Calculate the moles of reactant consumed and reaction products produced by using the molar ratios defined by the chemical equation. In this case, the equation shows that for every one mole of CH_4 consumed, two moles of O_2 are consumed, one mole of CO_2 is produced, and two moles of H_2O are produced.

Moles of CO_2 produced:	moles of CH_4 = moles of CO_2 6.25 moles CH_4 = 6.25 moles CO_2 **6.25 moles CO_2 produced**
Moles of H_2O produced:	2 x moles of CH_4 = moles of H_2O produced 2 x 6.25 moles CH_4 = 12.5 moles H_2O produced **12.5 moles H_2O produced**
Moles of O_2 reacted:	2 x moles of CH_4 = moles of O_2 reacted 2 x 6.25 moles CH_4 = 12.5 moles O_2 reacted **12.5 moles O_2 reacted**

(3) Calculate the flow rates of unknown input and output streams using the molecular weights for each of remaining streams. The molecular weights for CO_2, H_2O, and O_2 were calculated using method of step 1 above. The input flow rate of oxygen is supplied by:

Molecular weights:	CO_2 = 12 + 2 (16) = 44 kg/mol H_2O = 2 (1) + 16 = 18 kg/mol O_2 = 2 (16) = 32 kg/mol
kg of CO_2 produced:	6.25 moles CO_2 x 44 kg/mol = **275 kg CO_2**
kg of H_2O produced:	12.5 moles H_2O x 18 kg/mol = **225 kg H_2O produced**
kg of O_2 reacted:	12.5 moles O_2 x 32 kg/mol = **400 kg O_2 reacted**

(4) Calculate the input flow rate of air required to supply the needed oxygen. This quantity differs from the amount of O_2 reacted because air contains only 21 percent oxygen.

Composition of air:	21 percent Oxygen (O_2) 79 percent Nitrogen (N_2)
kg of air required:	400 kg O_2 ÷ 0.21 kg O_2/kg air = **1904.7 kg air**

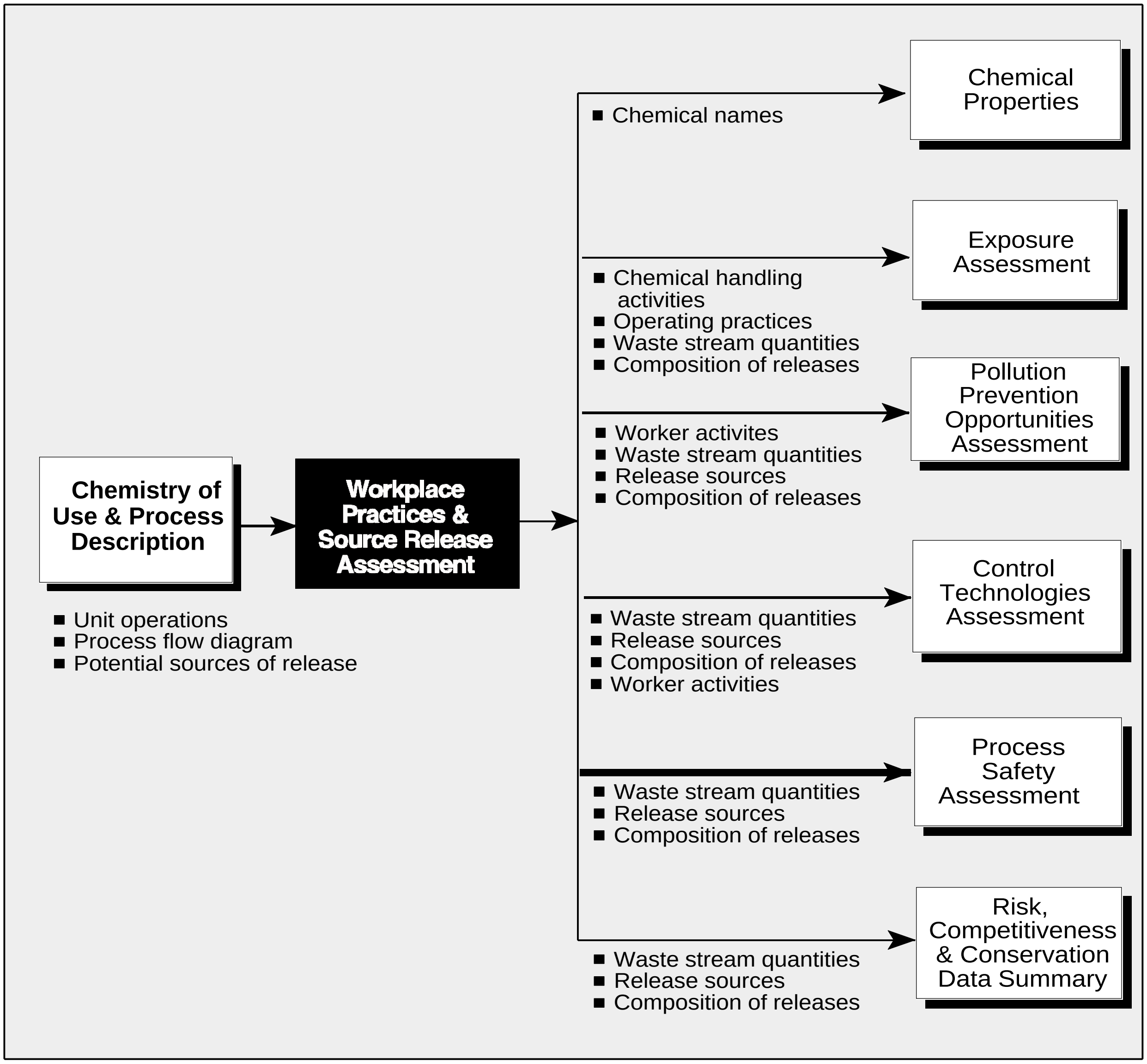
(5) Verify that the mass balance calculation was performed correctly by checking that the total mass of the input streams is equivalent to the total mass of the output streams (i.e., total mass is conserved).

Total kg of input streams:	100 kg CH_4 + 400 kg O_2 = 500 kg input material
Total kg of output streams:	275 kg CO_2 + 225 kg H_2O = 500 kg output material

500 kg Input material = 500 kg Output material

FLOW OF INFORMATION: In a CTSA, this module receives information from the Chemistry of Use & Process Description module and transfers information to the Chemical Properties, Exposure Assessment, Pollution Prevention Opportunities Assessment, Control Technologies Assessment, Process Safety Assessment, and Risk, Competitiveness & Conservation Data Summary modules. Example information flows are shown in Figure 6-3.

FIGURE 6-3: WORKPLACE PRACTICES & SOURCE RELEASE ASSESSMENT MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: Table 6-1 presents references for analytical models that can be used to perform a source release assessment.

TABLE 6-1: ANALYTICAL MODELS USED TO PERFORM A SOURCE RELEASE ASSESSMENT

Reference	Type of Model
U.S. Environmental Protection Agency. 1992b. *Strategic Waste Minimization Initiative (SWAMI) Version 2.0.*	Software tool for personal computers to aid in preparing a source release assessment.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 6-2 presents references for published guidance on source release assessments and the use of mass balances.

TABLE 6-2: PUBLISHED GUIDANCE ON SOURCE RELEASE ASSESSMENTS AND THE USE OF MASS BALANCES

Reference	Type of Guidance
Lorton, G.A., et. al. 1988. *Waste Minimization Opportunity Assessment Manual*.	Describes the EPA method for performing a source release assessment.
Luyben, William and L. Wenzel. 1988. *Chemical Process Analysis: Mass and Energy Balances*.	Describes the use of mass balances.
U.S. Environmental Protection Agency. 1987a. *Estimating Releases and Waste Treatment Efficiencies for the Toxic Chemical Release Inventory Form.*	Describes methods to determine waste streams by measurement, mass balance, or estimation.
U.S. Environmental Protection Agency. 1991e. *Chemical Engineering Branch Manual for the Preparation of Engineering Estimates.*	Describes various approaches and data sources for release estimation.
U.S. Environmental Protection Agency. 1992c. *User's Guide: Strategic Waste Minimization Initiative (SWAMI) Version 2.0.*	User's Manual for the SWAMI software package.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: None cited.

EXPOSURE ASSESSMENT

OVERVIEW: An exposure assessment is the quantitative or qualitative evaluation of the contact an organism (human or environmental) may have with a chemical or physical agent, which describes the magnitude, frequency, duration, and route of contact.

GOALS:

- Estimate occupational exposure to workers.
- Estimate consumer exposure from product use (if applicable).
- Estimate exposure to humans and aquatic organisms from releases to the ambient environment.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of exposure assessment guidance and methodology, including in the context of an occupational setting.
- Understanding of chemical fate, transport modeling and exposure modeling.
- Background in chemistry and environmental science.
- Background in occupational health or industrial hygiene.

Within a business or a DfE project team, the people who might supply these skills include a chemist, environmental scientist, industrial hygienist, and/or chemical engineer.

Note: The analysis presented in this module should only be undertaken by someone with expertise in exposure assessment. Because of the complexity and multidisciplinary nature of exposure assessments, it may be necessary even for the experienced exposure assessor to seek assistance from others with expertise in certain areas of the assessment. Furthermore, peer-review of the completed exposure assessment is recommended.

DEFINITION OF TERMS:

Acute Exposure: Exposure occurring over a short period of time (e.g., 14 days or less for fish). The specific time period varies depending on the test method and test organism or the receptor of interest.

Acute Potential Dose Rate (APDR): The dose, usually expressed on a per day basis, averaged over a period of time corresponding to an acute exposure period.

Averaging Time (AT): The time period, usually expressed in units of days, over which exposure is averaged when calculating an average dose rate.

Bioconcentration Factor (BCF): The equilibrium ratio of the concentration of a chemical in an exposed organism to the concentration of the chemical in the surrounding water.

Chronic Exposure: Continuous or intermittent exposure occurring over an extended period of time, or a significant fraction of the animal's or the individual's lifetime (e.g., > 20 days for daphnids).

Contact Rate (CR): The amount of contaminated medium contacted per unit time or event (e.g., m^3 per day of air inhaled, liters per day of water ingested).

Dose: See Potential Dose Rate.

Exposure: The contact of an organism (human or environmental) with a chemical or physical agent, expressed in terms of concentration and time.

Exposure Concentration, Exposure Point Concentration: The chemical concentration, in its transport or carrier medium, at the location of contact with an organism. Also defined, typically for exological risk, as the *Expected Environmental Concentration* (EEC) or *Predicted Environmental Concentration* (PEC).

Exposure Descriptor: A term used to characterize the position an exposure estimate has in the distribution of possible exposures (e.g., high-end, central tendency) for the population of interest.

Exposure Duration (ED): The duration of exposure, typically expressed in terms of days or years.

Exposure Frequency (EF): The frequency of exposure, expressed in units of days per year, events per year, events per lifetime, etc.

Exposure Level: In general, a measure of the magnitude of exposure, or the amount of an agent available at the exchange boundaries (i.e., lungs, gastrointestinal tract, or skin), during some specified time. In the Exposure Assessment and Risk Characterization modules, "exposure level" is used specifically as a measure of exposure expressed as a concentration rather than as a potential dose rate.

Exposure Pathway: The physical course a chemical takes from the source to the organism exposed. An example of an exposure pathway might be inhalation by a worker of volatile organic compounds (VOCs) that have evaporated from a solvent to the air.

Exposure Point: The location of potential contact between an organism and a chemical or physical agent.

Exposure Route: The route by which a chemical (or physical agent) comes in contact with the body of a receptor (e.g., by inhalation, ingestion, or dermal contact).

Exposure Scenario: A description of the specific circumstances under which exposure might occur, consisting of facts, assumptions, and inferences about how exposure takes place. An exposure scenario may comprise one or more exposure pathways.

Exposure Setting: The time frame and location, including a facility and its surrounding environment, where exposure might occur.

Lifetime Average Daily Concentration (LADC): The estimated daily concentration (usually in air) during the exposure duration, averaged over a lifetime.

Lifetime Average Daily Dose (LADD): The estimated potential daily dose rate received during the exposure duration, averaged over a lifetime. LADD is typically expressed in units of mg/kg-day.

Peak Exposure Level or Dose: The maximum exposure level or maximum potential dose rate.

Potential Dose Rate (PDR): The amount of a chemical ingested, inhaled, or applied to the skin per unit time (e.g., in units of mg/day). PDR may also be expressed per unit body weight per unit time (e.g., in mg/kg-day). PDR is the amount of a chemical that is available at the body's exchange boundaries and potentially could be absorbed into the body. (Related terms used elsewhere include "intake" or simply "dose," although the term dose implies that absorption is taken into account while PDR does not. The concepts of intake, dose and potential dose are described in detail in "Guidelines for Exposure Assessment" [EPA, 1992a].)

Receptor: The organism of interest (human or non-human) involved in a particular exposure pathway.

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for conducting an exposure assessment. Further details on Steps 2, 3, 5, 6, 7, 8, and 9 are presented in the next section of this module. It should be noted that this is intended as a simplified overview of the exposure assessment process, which will vary on a case-by-case basis. The reader is referred to guidance documents (see Table 6-8) for further information. The guidance documents alone, however, do not substitute for experience; professional judgement plays an important role in the exposure assessment process, as stated in "Guidelines for Exposure Assessment" (EPA, 1992a)*:*

> *"Exposure assessments are done for a variety of purposes and for that reason, cannot easily be regimented into a set format or protocol." ... "Professional judgement comes*

> *into play in virtually every aspect of the exposure assessment process, from defining the appropriate exposures scenarios, to selecting the proper environmental fate models, to determining representative environmental conditions, etc."*

With these caveats, the steps involved in exposure assessment are summarized below.

Step 1: Identify the potentially exposed population(s), including any sensitive or highly exposed subpopulation(s). For example, populations may include workers in a facility and residents living near a facility; special subpopulations may include children, the elderly, or residents living especially close to a facility. Occupational and population exposures are evaluated separately.

Step 2: Characterize the exposure setting. This includes characterizing the physical environment, all waste streams, and defining the exposure scenarios to be evaluated for the identified population(s). Collect information on the exposure setting from the Chemistry of Use & Process Description and the Workplace Practices & Source Release Assessment modules, and the Industry and Use Cluster Profile (see Chapter 2).

Step 3: Based on the characterization from Step 2, evaluate any possible exposure pathways and select complete exposure pathways to evaluate. Collect information pertaining to exposure pathways from the Workplace Practices & Source Release Assessment and Environmental Fate Summary modules. The potential for population exposures should be evaluated for releases to water, releases to air, and releases to land.

Step 4: Perform a literature search for available chemical concentration data, such as chemical concentrations in indoor air.

Step 5: Estimate concentrations in all media where exposure could occur. (For the aquatic exposure assessment, estimate concentrations in water where exposure to aquatic organisms could occur.) Concentrations can be from measured data and/or estimated using chemical fate and transport models. Use information from the previous steps, the Industry and Use Cluster Profile, and the following modules to estimate concentrations: Chemical Properties, Environmental Fate Summary, Workplace Practices & Source Release Assessment, Performance Assessment, and Control Technologies Assessment.

Step 6: Select values for exposure parameters used to estimate PDR for the population(s) of interest, clearly documenting the data sources and any assumptions made. Collect information pertaining to occupational exposure parameters from the Workplace Practices & Source Release Assessment module.

Step 7: Quantify exposure either in terms of PDR or exposure level.

Step 8: Evaluate uncertainties.

Step 9: Provide exposure information to the Human Health Hazards Summary, Risk Characterization, and Risk, Competitiveness & Conservation Data Summary modules.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 2, 3, 5, 6, 7, 8, and 9. Additional information on these and other steps can be found in the previously published guidance (see Table 6-8: Published Guidance on Exposure Assessment). In addition, detailed examples of occupational exposure assessment and population exposure assessment are presented in Appendix B and C, respectively, from the Screen Reclamation CTSA (EPA, 1994c).

Details: Step 2, Characterizing the Exposure Setting

This involves characterizing the physical setting with regard to actual or potential exposure for the population(s) of interest (e.g., workers, consumers, persons exposed through releases to the ambient environment, and aquatic organisms). In a CTSA, some of this characterization is performed in other modules. An evaluation of the process flow or the unit operations involved in the use cluster is performed in the Chemistry of Use & Process Description module. The Workplace Practices & Source Release Assessment module provides information on the occupational setting and worker activities required to characterize worker population exposure (e.g., number of workers, job descriptions), the chemical release/emission points, and the quantity of chemical released for a "model" or "sample" facility, as well as the media to which the chemical is released.

Information on product use by consumers, and land use and demographic data for areas surrounding the facilities and other release points could be used to assess potential exposures to other human populations. Additional information on the location of aquatic environments might be used to assess exposure to aquatic organisms, and to humans through the food chain.

Characterizing the exposure setting leads to defining exposure scenarios to be evaluated. Some example scenarios include:

- Nearby residents using groundwater in their homes that has been contaminated by releases from a landfill.
- Consumers bringing dry-cleaned clothes into their homes, potentially exposing themselves to perchloroethylene.
- Workers in a facility using a specific piece of equipment or performing a specific process.

Many other exposure scenarios are possible, and are very case-specific. The definition of exposure scenarios leads to selection of the exposure pathways to be evaluated. An exposure scenario may comprise one or several pathways.

Example data elements that may be used to characterize the exposure setting and define the exposure scenarios are listed below, along with sources of those data.

- *Sizes for small and medium facilities:* from the Workplace Practices & Source Release Assessment module.
- *Average number of workers at a facility*: from the Workplace Practices & Source Release Assessment module.
- *Total population of workers in the industry*: from the Workplace Practices & Source Release Assessment module, the Industry and Use Cluster Profile, and other sources (e.g., industry sources, census data, National Institute for Occupational Safety and Health [NIOSH], Health Hazard Evaluations [HHE]).
- *Operations/activities in handling the chemicals*: from the Workplace Practices & Source Release Assessment module, professional judgement, and other sources (e.g., NIOSH HHE, industry sources).
- *Chemical fate in the environment*: from the Environmental Fate Summary module.

Details: Step 3, Selecting Exposure Pathways

Selection of exposure pathways involves professional judgement and is based on the characterization of the physical setting, potentially exposed populations, and exposure scenarios from Steps 1 and 2. All of the pathways considered should be documented, with reasons for selection or exclusion of each pathway. A complete exposure pathway consists of:

- A source of chemical and mechanism for release.
- An exposure point.
- A transport medium (if the exposure point differs from the source).
- An exposure route.

For example, an occupational exposure pathway in a printing shop could consist of volitization of lacquer thinner from an open container as the source and mechanism of release; a worker's breathing zone as the exposure point; air as the transport medium (transport from the container to the worker's breathing zone); and inhalation as the exposure route.

Typical exposure pathways evaluated for occupational exposure are inhalation of airborne chemicals and dermal contact. Typical exposure pathways evaluated for human exposures in the ambient environment are:

- Inhalation of chemicals in air.
- Ingestion of chemicals in drinking water, from either groundwater or surface water.
- Ingestion of fish that have been exposed to bioaccumulative chemicals. EPA's Exposure Assessment Branch generally assumes that chemicals with a BCF of > 100 will bioaccumulate. (BCF values come from the Environmental Fate Summary module.)

Other pathways are possible, and will vary on a case-by-case basis. Other possible pathways might include:

- Ingestion of mother's milk by an infant, where the mother has been exposed to the chemical(s) of interest.

- Incidental ingestion of soil by nearby residents where the soil has been contaminated by releases from a nearby facility.
- Inhalation of VOCs from household water use.

Additional data elements that may be used to select occupational exposure pathways, and sources of those data, are listed below.
- *Personal protective equipment used*: from the Workplace Practices & Source Release Assessment module, using professional judgement, and checked against other sources of information.
- *Types of engineering controls used to reduce exposures (e.g., ventilation)*: from the Workplace Practices and Source Release Assessment module, professional judgement, and other sources of information (e.g., NIOSH HHE, Material Safety Data Sheets [MSDSs]).

Details: Step 5, Estimating Concentrations

Exposure concentrations can be determined by measurements or by fate and transport models (see Table 6-7: Analytical Models Used in Exposure Assessment). Selection of fate and transport models depends in part on the available data and on the data needs for the exposure assessment. Typical data sources for exposure assessment, listed in order of preference, include:
- Actual monitoring data for the compound of interest at the location where exposure could occur.
- Monitoring data for a similar process.
- Models to estimate worker exposures and environmental releases.
- Administrative controls and permit requirements to roughly estimate exposure and/or releases.

Additional data elements that may be used to estimate exposure concentrations, and sources of those data, are listed below.
- *Chemical formulations*: from the Performance Assessment module.
- *Amount of chemical used per day*: from the Workplace Practices & Source Release Assessment module and professional judgement.
- *Media of release*: from the Workplace Practices & Source Release Assessment module and types of control technologies used to reduce releases/exposures.
- *Amount of releases per site-day*: data for waste streams that can be quantified are obtained from the Workplace Practices & Source Release Assessment module; other release rates are modeled in the exposure assessment using information on conditions for potential releases from the Workplace Practices & Source Release Assessment module.
- *Number of shifts run per day and number of operating days*: from the Workplace Practices & Source Release Assessment module.
- *Number of facilities in the industry*: from the Workplace Practices & Source Release Assessment module, the Industry and Use Cluster Profile, and other sources (e.g., industry sources, census data, NIOSH HHE).

- *Total industry releases per year*: determined from amount of releases per site-day, number of facilities in the industry, number of shifts run per day, and number of operating days.
- *Pretreatment standards and discharge permits*: from the Workplace Practices & Source Release Assessment module or other sources.
- *Types of control technologies used to reduce releases and subsequent exposures*: from the Control Technologies Assessment and Workplace Practices & Source Release Assessment modules.
- *Frequency and duration of releases*: determined from number of shifts run per day, number of operating days, and duration of potential exposures.
- *Chemical fate in the environment* (specifically, chemical/physical parameter values used for transport modeling/exposure determination): from the Chemical Properties and Environmental Fate Summary modules.

Below is an example format for documenting the point-of-contact concentrations used in the exposure assessment.

Population(s) of Interest/Pathways	Chemical	Exposure Concentration	Comments (e.g., Details, Assumptions)
Workers, inhalation of VOCs in air.	chemical *a* . . . chemical z	conc. *a* (mg/m^3) . . . conc. *z* (mg/m^3)	Concentrations estimated using a volatilization model and average measured concentrations in solution x.

Table 6-3 is an example of calculating and presenting surface water concentrations from releases to water from a single facility.

TABLE 6-3: EXAMPLE - ESTIMATED RELEASES TO WATER FROM TRADITIONAL FORMULATIONS FROM SCREEN RECLAMATION AT A SINGLE FACILITY[a]

Substance	Amount Released to Water From Facility (g/day)	Waste Water Treatment Removal Efficiency	Amount to Water After Waste Water Treatment (g/day)	Daily Stream Concentration, for 1,000 MLD Receiving Water (µg/l)[b]
Methyl ethyl ketone	363	84%	58	0.06
n-Butyl acetate	191	97%	5.7	0.006
Methanol	37	97%	1.1	0.001
Naptha, light aliphatic	257	94%	15.4	0.02
Toluene	251	92%	20	0.02
Isobutyl isobutyrate	132	98%	2.6	0.003

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) µg/l is micrograms per liter, which is parts per billion for a substance in water. MLD is million liters per day.

In some areas there may be several facilities connected to the same waste water treatment plant. The concentration in the stream would be the combined amounts of all the releases in the stream.

As an example, the combined effects of multiple screen printing facilities in St. Louis County, Missouri, were demonstrated in the Screen Reclamation CTSA. Dun and Bradstreet data showed 135 screen printing facilities in St. Louis County. It was assumed that the waste water from all of these facilities goes to the St. Louis County Sewer Company, which releases into the Meramec River. Table 6-4 presents the surface water concentrations for the combined facilities' releases.

TABLE 6-4: EXAMPLE - ESTIMATED CUMULATIVE RELEASES FOR ST. LOUIS COUNTY, MISSOURI, FROM 135 SCREEN PRINTING FACILITIES[a]

Substance	Total Amount Released to Water From All Facilities (kg/day)	Waste Water Treatment Removal Efficiency	Amount to Water After Waste Water Treatment (g/day)	Average Concentration in Meramec River, (µg/l)[b]
Methyl ethyl ketone	49	84%	7,800	1
n-Butyl acetate	26	97%	800	0.1
Methanol	5	97%	150	0.02
Naptha, light aliphatic	35	94%	2,100	0.3
Toluene	34	92%	2,700	0.3
Isobutyl isobutyrate	18	98%	360	0.04

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) µg/l is micrograms per liter, which is parts per billion for a substance in water. The mean flow of the river is 7,895 MLD (million liters per day).

Table 6-5 is an example of calculating and presenting air concentrations from releases to air.

TABLE 6-5: EXAMPLE - AIR RELEASES AND CONCENTRATIONS FROM A SINGLE MODEL SCREEN PRINTING FACILITY[a]

Substance	Amount of Releases per Day (g/day)	Highest Average Concentration at 100 Meters[b] ($\mu g/m^3$)
Methyl ethyl ketone	403	0.8
n-Butyl acetate	107	0.2
Methanol	101	0.2
Naptha, light aliphatic	222	0.4
Toluene	255	0.5
Isobutyl isobutyrate	19.7	0.04

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) This estimates air concentrations at 100 meters from a hypothetical facility. The actual number of people who would fall into this range can be determined from census data, if the facility location is known. The model used to calculate concentrations is explained in the Screen Reclamation CTSA, Overview by Media - Air Section in Appendix C.

Details: Step 6, Selecting Values for Exposure Parameters for the Population(s) of Interest

Typical required parameters include:
- Contact rate (CR) (e.g., water ingestion, inhalation, or dermal contact rates).
- Exposure frequency (EF).
- Exposure duration (ED).
- Body weight (BW).
- Averaging time (AT).

Additional data elements that may be used to determine parameter values for quantifying worker exposure are listed below, along with the appropriate sources.
- *Duration of potential exposures*: from the Workplace Practices & Source Release Assessment module.
- *Frequency of exposures*: from the Workplace Practices & Source Release Assessment module, with professional judgement required to interpret the applicability of survey information.
- *Number of shifts run per day and number of operating days:* from the Workplace Practices & Source Release Assessment module.

If data are not available, professional judgement may be used to select default parameter values. See Table 6-9: Sources of Data for Exposure Assessment, for documents containing measured or default values for exposure parameters.

Following is an example format for documenting the parameters and assumptions used in the exposure assessment.

Population/ Pathways	Parameter	Value, Units	Reference, Rationale
Workers in Ocupational Setting			
Inhalation of VOCs	inhalation rate exposure frequency exposure duration body weight averaging time	__ m^3/day __ days/year __ years __ kg __ days	Information from the Workplace Practices & Source Release Assessment module or default values from EPA guidance (e.g., EPA, 1990a; EPA, 1991f).
Adults in a Residential Setting			
Inhalation of VOCs Released from Site	inhalation rate exposure frequency exposure duration body weight averaging time	__ m^3/day __ days/year __ years __ kg __ days	Information from the Workplace Practices & Source Release Assessment module or default values from EPA guidance (e.g., EPA, 1990a; EPA, 1991f).

Note: Default values are not presented. Exposure frequency and exposure duration for workers are typically determined from the Workplace Practices & Source Release Assessment module.

Details: Step 7, Quantifying Exposure

The concentration and other parameter values selected in Steps 5 and 6 are used to quantify exposure in pathway-specific exposure equations. Equations for several pathways can be found in "Guidelines for Exposure Assessment" (EPA, 1992a), *Risk Assessment Guidance for Superfund* (EPA, 1989a), and in *Dermal Exposure Assessment: Principles and Applications* (EPA, 1992d). A generic equation for quantifying exposure is:

PDR = (C)(CR)(EF)(ED)/[(BW)(AT)]

where:

PDR	=	potential dose rate (mg/kg-day) (LADD, APDR or other dose rate)
C	=	chemical concentration in exposure medium (average or peak concentration contacted during the exposure period)
CR	=	contact rate; the amount of contaminated medium contacted per unit time or exposure event (i.e., m^3/day of air inhaled, L/day of water ingested, etc.)
EF	=	exposure frequency (days/year)
ED	=	exposure duration (years); exposure frequency and duration may also be combined into one term, also called exposure frequency but expressed in units of days
BW	=	body weight; the average body weight over the exposure period (kg)
AT	=	averaging time; the time period, in days, over which exposure is averaged

For example:

For a chemical concentration of 5 mg/L in water, 2 liters of water ingested per day, an exposure frequency of 365 days per year, an exposure duration of 9 years, a body weight for an adult of 70 kg, and an averaging time of 25,550 days (for a 70-year lifetime), the LADD for ingestion of drinking water is typically calculated as follows:

LADD = (5 mg/L)(2 L/day)(365 days/year)(9 years)/[(70 kg)(25,550 days)]
= 0.018 mg/kg-day

An acute PDR can also be calculated using an exposure frequency and duration, and an averaging time of one day:

APDR = (5 mg/L)(2 L/day)(1 day)/[(70 kg)(1 day)]
= 0.14 mg/kg-day

An example of occupational exposure results is shown in Table 6-6.

TABLE 6-6: EXAMPLE - OCCUPATIONAL EXPOSURE ESTIMATES FOR SCREEN RECLAMATION, INK REMOVER SYSTEM[a]						
Substance	**Inhalation (mg/day)[b]**				**Dermal (mg/day)**	
	I	**II**	**III**	**IV**	**Routine**	**Immersion**
Methyl ethyl ketone	165	5.3	3	20	468	2,180
n-Butyl acetate	44	1.3	1	5.3	234	1,090
Methanol	27	4.7	2	15	78	364
Naptha, light aliphatic	98	1.6	1	6.2	312	1,460
Toluene	110	2.3	1	9.2	312	1,460
Isobutyl isobutyrate	7	0.4	0	1.7	156	728

a) Example taken from Screen Reclamation CTSA (EPA, 1994c).
b) Scenario I = reclaiming 6 screens per day; each screen is approximately 2100 in^2; Scenario II = pouring 1 ounce of fluid for sampling; Scenario III = transferring chemicals from a 55 gallon drum to a 5 gallon pail; Scenario IV = storing waste rags in a drum and transferring them to a laundry.

Details: Step 8, Evaluating Uncertainties

A discussion of uncertainties in the overall risk assessment process is presented in the Risk Characterization module. Sources of uncertainty in the exposure assessment could include:

- Description of exposure setting - how well the typical facility used in the assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been evaluated, including minor ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgement.
- Uncertainty in combining pathways for an individual.

In a CTSA, uncertainty is typically addressed qualitatively. Because of the uncertainty inherent in the parameters and assumptions used in estimating exposure, and the variability that is possible within a population, there is no one number that can be used to describe exposure. Using exposure (or risk) descriptors is a method typically used to provide information about the position an exposure estimate has in the distribution of possible outcomes for a particular population. "Guidelines for Exposure Assessment" (EPA, 1992a), Habicht (1992), and others provide guidance on the use of risk descriptors, which include the following:

- *Central tendency*: represents either an *average estimate* (based on average values for the exposure parameters) or a *median estimate* (based on 50th percentile or geometric mean values) of the actual distribution.

- *High-end*: represents approximately the upper 10th percentile of the actual (measured or estimated) distribution. The high-end descriptor is a plausible estimate of individual risk for those persons at the upper end of the exposure distribution (i.e., a person exposed to an amount higher than 90 percent of the people who are exposed to the substance). It is also no higher than the individual in the population who has the highest exposure.
- *Bounding estimate*: an intentional overestimate of exposure used for screening purposes. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.
- *Worst case*: a combination of events and conditions such that, taken together, produces the highest conceivable risk.
- *What-if*: represents an exposure estimate based on postulated questions (e.g., what if the worker is exposed to the concentration predicted by a particular air dispersion model). The estimates based on these what-if scenarios do not give any indication as to the likelihood of the exposure actually occurring, but may be useful for decision-making or to add perspective to the risk assessment.

Two types of quantitative uncertainty analysis (discussed in EPA, 1990a and EPA, 1992a) are sensitivity analysis and probability analysis. Sensitivity analysis requires data on the range of exposure parameter values, and gives information on how the results are impacted by variation within the different parameters. Sensitivity analysis can be used to determine the percent contribution to the overall uncertainty and/or variability from specific exposure parameters. Probability analysis (e.g., Monte Carlo simulation) requires data on the range and probability function, or distribution, of the exposure parameters and yields a probability function that describes the range of possible results. (Although not generally recommended for a CTSA, the increasing use of Monte Carlo simulation and availability of software for performing this type of analysis warrants mention of the technique.)

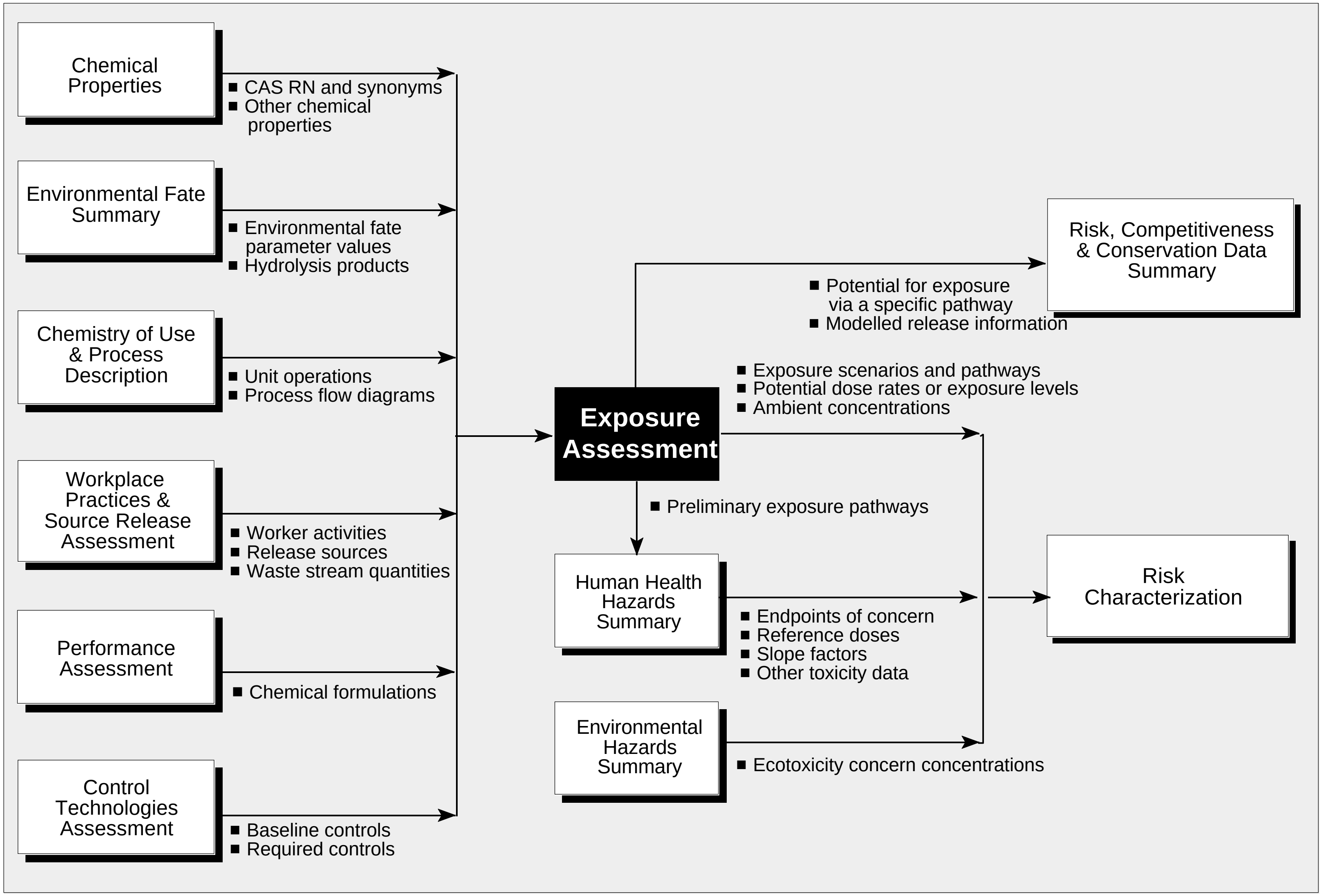
Details: Step 9, Transferring Information

Data elements that are transferred from the Exposure Assessment module are listed below:

- *Preliminary exposure pathways*: to the Human Health Hazards Summary module.
- *Exposure scenarios and pathways, ambient aquatic exposure concentrations, PDR, human exposure levels, and uncertainty information*: to the Risk Characterization module.
- *Modeled release information (i.e., releases not quantified in the Workplace Practices & Source Release Assessment module but modeled in the Exposure Assessment module instead, such as releases of VOCs from containers of solvent left open during operating hours) and potential for exposure (e.g., high, medium, low) via a particular pathway (e.g., inhalation, ingestion, dermal):* to the Risk, Competitiveness & Conservation Data Summary module.

To the extent possible, include "unit of production" information with the exposure assessment results. For example, report the square feet of printed wiring board produced during the time period corresponding to the PDR. This can be determined by multiplying ED (in years) by the production rate (in ft^2/year). This may not be possible in all cases, depending on the available data. This information is used in the Risk Characterization module to express risk on a "per unit of production" basis.

FLOW OF INFORMATION: The Exposure Assessment module receives information from the Chemical Properties, Environmental Fate Summary, Chemistry of Use & Process Description, Workplace Practices & Source Release Assessment, Performance Assessment, and Control Technologies Assessment modules. It transfers information to the Human Health Hazards Summary, Risk Characterization, and Risk, Competitiveness & Conservation Data Summary modules. Examples of information flows are shown in Figure 6-4.


Chemical Properties
■ CAS RN and synonyms
■ Other chemical properties
Environmental Fate Summary
■ Environmental fate parameter values
■ Hydrolysis products
Chemistry of Use & Process Description
■ Unit operations
■ Process flow diagrams
Workplace Practices & Source Release Assessment
■ Worker activities
■ Release sources
■ Waste stream quantities
Performance Assessment
■ Chemical formulations
Control Technologies Assessment
■ Baseline controls
■ Required controls
Exposure Assessment
■ Potential for exposure via a specific pathway
■ Modelled release information
Risk, Competitiveness & Conservation Data Summary
■ Exposure scenarios and pathways
■ Potential dose rates or exposure levels
■ Ambient concentrations
■ Preliminary exposure pathways
Human Health Hazards Summary
■ Endpoints of concern
■ Reference doses
■ Slope factors
■ Other toxicity data
Environmental Hazards Summary
■ Ecotoxicity concern concentrations
Risk Characterization

ANALYTICAL MODELS: Table 6-7 presents references for analytical models that can be used to estimate exposure concentrations. This list contains the major models used by the U.S. EPA Office of Pollution Prevention and Toxics, in the Exposure Assessment Branch, for their work, and is not all-inclusive.

Note: Chemical fate and transport modeling is a highly technical undertaking, and should be performed only by someone with the appropriate technical background and experience with the particular models to be used. Additional sources of information on models includes the Integrated Model Evaluation System (IMES), developed by the Office of Research and Development within the U.S. EPA. IMES is currently undergoing review by EPA and is available to assist in the selection of appropriate fate models.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
AMEM (A.D. Little Migration Estimation Model): A.D. Little, Inc. Lastest version, 1993.	Multimedia environmental fate; models migration of additives, monomers, and oligomers from polymeric material.
AT123D[a,b] (Analytical Transient One-, Two-, and Three-Dimensional Simulation model): Yeh, G.T. 1981. *AT123D: Analytical Transient One-, Two-, and Three-Dimensional Simulation of Waste Transport in an AQUIFER System.*	Groundwater model; estimates spread of contaminant plume through saturated zone, considers adsorption and degradation.
BOXMOD[a]: General Sciences Corporation. 1991a. *GEMS User's Guide.*	Air model; estimates exposure in urban areas with diffuse emissions. BOXMOD is implemented in the Graphical Exposure Modeling System (GEMS).
DERMAL: Versar, Inc. 1995a. *DERMAL User's Manual.*	Estimates consumer dermal exposure for a variety of product categories.
ENPART[a,b]: General Sciences Corporation. 1985a. *A User's Guide to Environmental Partitioning Model.*	Multimedia environmental fate model to screen for chemical partitioning in the environment.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
EXAMS-II[a,b] (Exposure Analysis Modeling System): Burns, L.A., et al. 1982. *Exposure Analysis Modeling System (EXAMS) User Manual and System Documentation*. Burns, L.A., et. al. 1985. *Exposure Analysis Modeling System: User's Guide for EXAMS II*.	Surface water model; simulates fate, transport, and persistence of organic chemicals in surface water.
FLUSH: Versar, Inc. 1995b. *FLUSH User's Manual*.	Surface water model; estimates surface water concentrations from disposal of household products.
Fugacity models: For example: Mackay, D. 1993. *Multimedia Environmental Models, The Fugacity Approach*.	Multimedia fate and transport models.
GAMS[a] (GEMS Atmospheric Modeling Subsystem): General Sciences Corporation. 1990a. *Draft GAMS Version 3.0 User's Guide*.	Air exposure model; estimates average annual concentrations, LADD and risks; incorporates ISCLT and TOXBOX as the air fate and transport models.
GEMS/PCGEMS (Graphical Exposure Modeling System): General Sciences Corporation. 1988a. *PCGEMS User's Guide Release 1.0*. General Sciences Corporation. 1991b. *Graphical Exposure Modeling System, GEMS User's Guide*. Harrigan, P. and A. Battin. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in Surface Waters*. Harrigan, P. and A. Nold. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in Unsaturated Soil and Groundwater*. Harrigan, P. and S. Rheingrover. 1989. *Training Materials for GEMS and PCGEMS: Estimating Chemical Concentrations in the Atmosphere*.	Modeling system for general population exposure assessment. Includes fate and transport models along with some relevant data needed to run those models, and where possible applies results to assess the population exposed. Includes many of the models listed below, as well as population data.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
INPUFF[a]: General Sciences Corporation. 1986. *INPUFF User's Guide*.	Air model; estimates air exposure from short term releases or continuous plume.
ISCLT[a,b] (Industrial Source Complex Long-Term), and ISCST[a] (Industrial Source Complex Short-Term): U.S. Environmental Protection Agency. 1992e. *Industrial Source Complex (ISC2) Dispersion Models User's Guide*.	Air model; ISCLT calculates average annual air concentrations and exposures. Air model; ISCST calculates short term air concentrations and exposures.
MCCEM (Multi-Chamber Concentration and Exposure Model): Geomet Technologies, Inc. 1991a. *MCCEM User's Manual, Version 2.3*. Geomet Technologies, Inc. 1991b. *MCCEM Documentation Model, Version 2.3*.	Air model; estimates consumer inhalation exposure.
PDM 3.1 (Probabilistic Dilution Model): Versar, Inc. UNDATED. *User's Guide to PDM 3.1*.	Surface water model; estimates frequency that concentration of concern is exceeded.
PRZM[a,c] (Pesticide Root Zone Model): Carsel, R.F., et. al. 1984. *Users Manual for the Pesticide Root Zone Model (PRZM) Release 1*.	Soil model; simulates vertical transport in the vadose zone, plant uptake, runoff, etc.
PTPLU[a,b] (Point Plume): General Sciences Corporation. 1988b. *User's Guide for PTPLU in GEMS*. Pierce, T.E. and D.B. Turner. 1982. *PTPLU - A Single Source Gaussian Dispersion Algorithm User's Guide*.	Air model; calculates maximum short term air concentrations.
ReachScan: Versar, Inc. 1992a. *ReachScan User's Manual*.	Surface water model; estimates downriver concentrations and exposures.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
ReachScan/PDM: Versar, Inc. 1992b. *ReachScan/PDM User's Manual*.	Surface water model; combines downriver concentration estimates from REACHSCAN with the concentration of concern (COC) exceedance information from PDM.
SCIES (Screening Consumer Inhalation Exposure Software): Versar, Inc. 1994. *SCIES User's Manual, Version 3.0*.	Air model; estimates consumer inhalation exposure for a variety of product categories.
SEAS (Screening Exposure Assessment Software): U.S. Environmental Protection Agency. 1995e.	Surface water concentration estimation; simple dilution calculations from flow data. Calculates by single facility or by groupings of Standard Industrial Classifications (SICs). SIC-based stream information used to calculated mean and low flows for the industry.
SESOIL[a,b] (Seasonal Soil Compartment Model): Bonazountas, M. and J. Wagner. 1981. *SESOIL, a Seasonal Soil Compartment Model.*	Soil/vadose zone model; long-term fate simulations for organic and inorganic chemicals.
STP (Sewage Treatment Plant fugacity model): Clark, B., et al. 1995. "Fugacity Analysis and Model of Organic Chemical Fate in a Sewage Treatment Plant."	Estimates chemical fate in sewage treatment plants.
SWIP[a] (Survey Waste Injection Program): General Sciences Corporation. 1985b. *User's Guide to SWIP Model Execution Using Data Management Supporting System*. U.S. Geological Survey. UNDATEDa. "Detailed Model Description and Capabilities." U.S. Geological Survey. UNDATEDb. "Revised Documentation for the Enhanced Model."	Groundwater model; estimates chemical or thermal pollutant transport and transformation in groundwater systems.
TOXBOX[a]: General Sciences Corporation. 1990a. *Draft GAMS Version 3.0 User's Guide*.	Air model; estimates air exposure levels over large areas from diffuse sources. Available only within the GEMS Atmospheric Modeling Subsection.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
TOXSCREEN[a,b]: Hetrick, D.M. and L.M. McDowell-Boyer. 1983. *User's Manual for TOX-SCREEN: A MultiMedia Screening-Level Program for Assessing the Potential of Chemicals Released to the Environment.*	Multimedia environmental fate; models fate of chemicals released to air, water, soil, or a combination.
TRIAIR[a]: General Sciences Corporation. 1990b. *Draft TRIAIR User's Guide*.	Air model; models dose and air concentrations using TRI data and ISCLT model. Must be run by OPPT personnel.
TRIWATER: General Sciences Corporation. 1990c. *Implementation of the T.R.I. Regional Surface Water Modeling System in GEMS*. General Sciences Corporation. 1993. *Final Report, GEMS and RGDS Linkage III, EPA Contract 68-d0-0080, Work Assignment No. 3-4*.	Surface water model; estimates surface water concentrations and risks from point source releases. Must be run by OPPT personnel.
UTM-TOX[a] (Unified Transport Model for Toxicants): Browman, M.G., et. al. 1982. *Formulations of the Physicochemical Processes in the ORNL Unified Transport Model for Toxicants (UTM-TOX), Interim Report*. General Sciences Corporation. 1985c. *Characterization of Data Base Requirements for Implementation of UTM-TOX Under GEMS: Parameter Sensitivity Study*. Patterson, M.R., et. al. 1984. *A User's Manual for UTM-TOX, the Unified Transport Model.*	Multimedia environmental fate; simulates dispersion of chemicals in soil, air, and water.
Valley[a]: Burt, E. 1977. *VALLEY Model User's Guide*. General Sciences Corporation. 1989. *User's Guide for Valley in GEMS*.	Air model; estimates 24-hour average air concentrations in complex terrain.

TABLE 6-7: ANALYTICAL MODELS USED IN EXPOSURE ASSESSMENT	
Reference	**Type of Model**
Other models as required; from various sources, for example: U.S. Environmental Protection Agency. 1988c. *Superfund Exposure Assessment Manual*.	

a) Model is implemented in GEMS.
b) Model is implemented in PCGEMS.
c) Model is available from other sources in a more recent version than the version implemented in GEMS.
Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

PUBLISHED GUIDANCE: Table 6-8 presents references for published guidance on exposure assessment. **Some of these documents may not have been published outside of EPA**.

TABLE 6-8: PUBLISHED GUIDANCE ON EXPOSURE ASSESSMENT	
Reference	**Type of Guidance**
Gilbert, R.O. 1987. *Statistical Methods for Environmental Pollution Monitoring*.	Guidance on statistical methods for summarizing and using environmental monitoring data.
Habicht, F.H. II. 1992. *Guidance on Risk Characterization for Risk Managers and Risk Assessors*.	Guidance for risk assessors on describing risk assessment results in EPA reports, presentations and decision packages; includes guidance on use of exposure descriptors.
Harrigan, P. 1994. *Guidelines for Completing the Initial Review Exposure Report*.	Information on models, assessing releases to various media, and environmental fate default values as well as guidance on assessing exposure to consumers from use of various products.
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*.	Detailed guidance for developing health risk information at Superfund sites; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1989b. *Toxic Chemical Release Inventory Risk Screening Guide*.	Guidance for risk screening for ranking and further evaluation.
U.S. Environmental Protection Agency. 1991e. *Chemical Engineering Branch Manual for the Preparation of Engineering Assessments.*	Describes various approaches and data sources for occupational exposure estimation.

TABLE 6-8: PUBLISHED GUIDANCE ON EXPOSURE ASSESSMENT	
Reference	**Type of Guidance**
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Standard default values for exposure parameter to be used in the Superfund remedial investigation/feasibility study process; may also apply to exposure assessments in general.
U.S. Environmental Protection Agency. 1992a. "Guidelines for Exposure Assessment."	EPA guidance on exposure assessment.
U.S. Environmental Protection Agency. 1992d. *Dermal Exposure Assessment: Principles and Applications. Interim Report*.	Guidance on procedures for assessment of dermal exposure pathways.
U.S. Environmental Protection Agency. 1992f. *EPA Supplemental Guidance to RAGS: Calculating the Concentration Term.*	Calculating exposure point concentrations from environmental sample data.
U.S. Environmental Protection Agency. 1992g. *RM1/RM2 Process Manual, Version 1.0*.	Guidance for exposure assessors on performing RM1 and RM2 exposure assessments.
U.S. Environmental Protection Agency. 1994g. *Guidelines for Completing the Initial Review Exposure Report - Final Draft*.	Guidance for preparation of initial exposure assessments for substances submitted under the Pre-manufacture Notification Program.
U.S. Environmental Protection Agency. 1994h. *Guidelines for Statistical Analysis of Occupational Exposure Data*.	Guidance on using occupational exposure data.
Versar, Inc. 1988. *The Nonexposure Aspects of Risk Assessment, An Introduction for the Exposure Assessor*, Final Draft.	Guidance on interpreting results.
Wood, P. 1991. *Existing Chemical Assignment/RM1 Exposure Report*.	Information on chemical properties, production and use information, and consumer uses (if applicable).

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Table 6-9 lists sources of data for exposure assessment.

TABLE 6-9: SOURCES OF DATA FOR EXPOSURE ASSESSMENT	
Reference	**Type of Data**
American Industrial Health Council. 1994. *Exposure Factors Sourcebook*.	Summary and evaluation of current scientific documentation and statistical data for various exposure factors used in risk assessments.

TABLE 6-9: SOURCES OF DATA FOR EXPOSURE ASSESSMENT	
Reference	**Type of Data**
Chambers of Commerce.	Number of businesses of interest within a specified area.
Dun and Bradstreet, various sources.	Business census information.
Eastern Research Group, Inc. 1992. *Inventory of Exposure-Related Data Systems Sponsored by Federal Agencies*.	Description of and contacts for other sources of exposure data.
Environmental monitoring data from various sources.	Air, water, other environmental concentrations.
GEMS/PCGEMS models.	Contains census data, chemical properties for SARA Title III chemicals, and default model parameters (chemical, environmental, population, and site property data).
Industry, trade associations.	Chemical release information, controls used.
National Institute for Occupational Safety and Health (NIOSH). UNDATEDb. *Health Hazard Evaluations.*	Occupational exposure data.
Open literature.	Other exposure parameter data, other fate and transport models, etc.
U.S. Census Bureau.	Population, demographic data, some information on activity patterns (e.g., average time in a residence, average tenure for different occupations, etc.).
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A).*	Detailed guidance for developing health risk information at Superfund sites, including values for exposure parameters; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1990a. *Exposure Factors Handbook*.	Data on human physiological and behavioral parameters.
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Standard default values for exposure parameter to be used in the Superfund remedial investigation/feasibility study process; may also apply to exposure assessments in general.
U.S. Environmental Protection Agency. 1992d. *Dermal Exposure Assessment: Principles and Applications. Interim Report*.	Guidance on assessment of dermal exposure.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

RISK CHARACTERIZATION

OVERVIEW: Risk characterization (also referred to in the CTSA process as risk integration) is the integration of hazard and exposure information to quantitatively or qualitatively assess risk. Risk characterization typically includes a description of the assumptions, scientific judgments, and uncertainties that are part of this process.

The level of risk characterization necessary in a CTSA varies depending on the differences between the substitutes being assessed in the use cluster. The risk characterization identifies, in a manner that facilitates decision-making, the areas of concern as they differ among the substitutes. Risks may vary in terms of magnitude, type, or domain of application. If the differences in risk among the substitutes are great, then a detailed, quantitative characterization of risk may not be necessary. If the differences in risk associated with the substitutes are more subtle, then a quantitative analysis may be necessary. The methods outlined here describe a more detailed, quantitative risk characterization.

GOALS:

- Integrate chemical hazard and exposure information to assess and compare risks from ambient environment, consumer, and occupational exposures.

- Provide risk estimates to the Risk, Competitiveness & Conservation Data Summary module.

- Present risk information and discuss uncertainty in a manner that assists in decision-making.

PEOPLE SKILLS: The following lists the types of skills or knowledge that are needed to complete this module.

- Knowledge of risk assessment guidance and methodology.

- Understanding of chemical exposures.

- Understanding of human, other mammalian, and aquatic toxicology.

- Ability to present and interpret the results of risk characterization for decision-making.

Within a business or a DfE project team, the people who might supply these skills include a risk assessment specialist.

Note: The analysis presented in this module should not be undertaken without the assistance of someone with expertise in human health and environmental risk assessment. Furthermore, peer-review of the completed risk characterization is recommended.

DEFINITION OF TERMS: Several terms from the Human Health Hazards Summary, Environmental Hazards Summary, and Exposure Assessment modules are used in the Risk Characterization module and are defined here as well.

Human Health Hazards Summary

Developmental Toxicity: Adverse effects produced prior to conception, during pregnancy, or during childhood. Exposure to agents affecting development can result in any one or more of the following manifestations of developmental toxicity: death, structural abnormality, growth alteration, and/or functional deficit. These manifestations encompass a wide array of adverse developmental end points, such as spontaneous abortion, stillbirths, malformations, early postnatal mortality, reduced birth weight, mental retardation, sensory loss and other adverse functional or physical changes that are manifested postnatally.

International Agency for Research on Cancer (IARC) Classification: A method for evaluating the strength of evidence supporting a potential human carcinogenicity judgment based on human data, animal data, and other supporting data. A summary of the IARC carcinogenicity classification system includes:

- Group 1: Carcinogenic to humans.
- Group 2A: Probably carcinogenic to humans.
- Group 2B: Possibly carcinogenic to humans.
- Group 3: Not classifiable as to human carcinogenicity.
- Group 4: Probably not carcinogenic to humans.

Lowest-Observed Adverse Effect Level (LOAEL): The lowest dose level in a toxicity test at which there are statistically or biologically significant increases in frequency or severity of adverse effects in the exposed population over its appropriate control group.

No-Observed Adverse Effect Level (NOAEL): The highest dose level in a toxicity test at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects in the exposed population over its appropriate control; some effects may be produced at this level, but they are not considered adverse, nor precursors to adverse effects.

Pharmacokinetics: The dynamic behavior of chemicals within biological systems. Pharmacokinetic processes include uptake, distribution, metabolism, and excretion of chemicals.

Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of the daily inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. RfCs are generally reported as a concentration in air (mg/m^3).

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of the daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious noncancer effects during a lifetime. RfDs are reported as mg/kg-day.

Risk: In general, risk pertains to the probability and severity of adverse effects (e.g., injury, disease, or death) under specific circumstances. In the context of a CTSA, risk is an expression of the likelihood of adverse health or environmental effects from a specific level of exposure; only cancer risk is estimated as a probability. (Also see Cancer Risk, Individual Risk and Population Risk.)

Slope Factor (q_1*): A measure of an individual's excess risk or increased likelihood of developing cancer if exposed to a chemical. It is determined from the upperbound of the slope of the dose-response curve in the low-dose region of the curve. More specifically, q_1* is an approximation of the upper bound of the slope when using the linearized multistage procedure at low doses. The units of the slope factor are usually expressed as 1/(mg/kg-day) or $(mg/kg\text{-}day)^{-1}$.

Unit Risk: The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water or 1 $\mu g/m^3$ in air (with units of risk per $\mu g/m^3$ air or risk per µg/L water).

Weight-of-Evidence Classification (EPA): In assessing the carcinogenic potential of a chemical, EPA classifies the chemical into one of the following groups, according to the weight-of-evidence from epidemiologic and animal studies:

- Group A: Human Carcinogen (sufficient evidence of carcinogenicity in humans).
- Group B: Probable Human Carcinogen (B1 - limited evidence of carcinogenicity in humans; B2 - sufficient evidence of carcinogenicity in animals with inadequate or lack of evidence in humans).
- Group C: Possible Human Carcinogen (limited evidence of carcinogenicity in animals and inadequate or lack of human data).
- Group D: Not Classifiable as to Human Carcinogenicity (inadequate or no evidence).
- Group E: Evidence of Noncarcinogenicity for Humans (no evidence of carcinogenicity in adequate studies).

(The "Proposed Guidelines for Carcinogen Risk Assessment" [EPA, 1996b] propose use of weight-of-evidence descriptors, such as "Likely" or "Known," "Cannot be determined," and "Not likely," in combination with a hazard narrative, to characterize a chemical's human carcinogenic potential - rather than the classification system described above.)

Environmental Hazards Summary

Aquatic Toxicity Concern Concentration (CC): The concentration of a chemical in the aquatic environment below which no significant risk to aquatic organisms is expected.

Exposure Assessment

Acute Potential Dose Rate (APDR): The dose, usually expressed on a per day basis, averaged over a period of time corresponding to an acute exposure period.

Exposure Concentration, Exposure Point Concentration: The chemical concentration, in its transport or carrier medium, at the location of contact with an organism. Also defined, typically for ecological risk, as the *Expected Environmental Concentration* (EEC), or *Predicted Environmental Concentration* (PEC).

Exposure Level: In general, a measure of the magnitude of exposure, or the amount of an agent available at the exchange boundaries (i.e., lungs, gastrointestinal tract, or skin), during some specified time. In the Exposure Assessment and Risk Characterization modules, "exposure level" is used specifically as a measure of exposure expressed as a concentration rather than as a potential dose rate.

Exposure Pathway: The physical course a chemical takes from the source to the organism exposed. An example of an exposure pathway might be inhalation by a worker of volatile organic compounds (VOCs) that have evaporated from a solvent to the air.

Exposure Scenario: A description of the specific circumstances under which exposure might occur, consisting of facts, assumptions, and inferences about how exposure takes place. An exposure scenario may comprise one or more exposure pathways.

Lifetime Average Daily Concentration (LADC): The estimated daily concentration (usually in air) during the exposure duration, averaged over a lifetime.

Lifetime Average Daily Dose (LADD): The estimated potential daily dose rate received during the exposure duration, averaged over a lifetime. LADD is typically expressed in units of mg/kg-day.

Peak Exposure Level or Dose: The maximum exposure level or maximum potential dose rate.

Potential Dose Rate (PDR): The amount of a chemical ingested, inhaled, or applied to the skin per unit time (e.g., in units of mg/day). PDR may also be expressed per unit body weight per unit time (e.g., in mg/kg-day). PDR is the amount of a chemical that is available at the body's exchange boundaries and potentially could be absorbed into the body. (Related terms used elsewhere include "intake" or simply "dose," although the term dose implies that absorption is taken into account while PDR does not. The concepts of intake, dose, and potential dose are described in detail in "Guidelines for Exposure Assessment" [EPA, 1992a].)

Receptor: The organism of interest (human or non-human) involved in a particular exposure pathway.

Risk Characterization

Cancer Risk: The probability of developing cancer over a lifetime as a result of exposure to a potential carcinogen. Cancer risk could be estimated for an individual or a population (see Individual Risk and Population Risk). The cancer risk estimated in a CTSA is the upper bound excess lifetime cancer risk.

Ecological Risk Indicator: The ratio of the exposure concentration (EEC or PEC) to the CC. In ecological risk characterization this approach is typically referred to as the ecological quotient method.

Hazard Index (HI): The sum of more than one hazard quotient for multiple chemicals and/or multiple exposure pathways. Calculation of HI assumes additivity of the chemical effects. This is valid only where the chemicals elicit the same effect by the same exposure route and mechanism of action.

Hazard Quotient (HQ): The ratio of potential rate (PDR) or exposure level for a single chemical over a specified time period to the RfD or RfC for that chemical derived from a similar exposure period.

Individual Risk: An estimate of the probability of an exposed individual experiencing an adverse effect, such as "1 in 1,000" (or 10^{-3}) risk of cancer.

Margin of Exposure (MOE): The ratio of the NOAEL or LOAEL to a PDR or exposure level.

Population Risk: An aggregate measure of the projected frequency of effects among all exposed people, such as "four cancer cases per year."

APPROACH/METHODOLOGY: The following presents a summary of the approach or methodology for conducting a risk characterization. Further details for Steps 1 through 9 are presented in the next section of this module. This summary is intended as an overview of the process, and may vary on a case-by-case basis. The reader is referred to guidance documents (see Table 6-11 for further information).

Step 1: Collect and organize information from the Exposure Assessment, Human Health Hazards Summary, and Environmental Hazards Summary modules.

Human Health Risk (occupational, consumer, etc.)

Step 2: For each chemical in a pathway, calculate the indicator of cancer risk and/or noncancer risk.

- For each chemical that is classified in the hazard summary as a carcinogen, estimate cancer risk.

- For each chemical that exhibits noncancer health effects and for which an RfD or RfC is available (note: this may include chemicals that are also classified as carcinogens), calculate the indicator of noncancer risk, expressed as an HQ.
- For chemicals without a RfD or RfC, calculate the indicator of noncancer risk, expressed as a MOE.

Step 3: For multiple chemicals (e.g., exposure to a formulation made up of a mixture of chemicals), calculate total cancer risk and the noncancer HI for each pathway, using the information from Step 2.

Step 4: If applicable, and exposure is possible via more than one pathway, combine risks across pathways that affect the same individual(s) over the same time periods by summing cancer risks and summing HQs or HIs.

Step 5: If applicable, calculate population cancer risk.

Step 6: Discuss and assess sources of uncertainty and variability of risk characterization results.

Step 7: Summarize and present the risk characterization results. The chemical- and pathway-specific results from Step 2 as well as totals from Steps 3 and 4 (if applicable) and population cancer risk from Step 5 (if applicable) should all be presented. (Large tables of data may be more appropriately included as an appendix to the Risk Characterization module.)

Environmental (aquatic) Receptors

Step 8: Compare CC for each chemical to the exposure concentration (EEC or PEC). Typically, this is done for the aquatic environment. A numerical indicator of ecological risk may also be calculated as the ratio of the exposure concentration to the CC. This approach is typically referred to as the ecological quotient method.

Transfer Information

Step 9: Provide human health and environmental risk information to the Risk, Competitiveness & Conservation Data Summary module. Express risk characterization information on a "per unit of production" basis, if applicable.

METHODOLOGY DETAILS: This section presents methodology details for completing Steps 1 through 9. Additional information on these and other steps can be found in the published guidance (see Table 6-11: Published Guidance on Risk Characterization). In addition, an example of background information on risk assessment is presented in Appendix D, from the Screen Reclamation CTSA (EPA, 1994c).

Details: Step 1, Collecting and Organizing Data

Data to be provided by the Human Health Hazards Summary module include:

- Characterization of chemicals by hazard type: carcinogenicity, acute or chronic toxicity, developmental toxicity, etc.
- q_1* or unit risk, and weight-of-evidence for chemicals classified as carcinogens.
- RfD and/or RfC for chemicals that exhibit noncancer toxicity.
- LOAEL or NOAEL for chemicals where an RfD or RfC is not available.
- Pharmacokinetic data (e.g., chemical absorption factors).

Data to be provided by the Environmental Hazards Summary module include the CC.

Data to be provided by the Exposure Assessment module include:

- Outline of exposure scenarios, population(s) of interest, and pathways to be evaluated (these are described in the Exposure Assessment module).
- Potential dose rates (e.g., the PDR, LADD, and APDR).
- Exposure levels (e.g., the lifetime average exposure level, and the peak exposure level [expressed as concentrations]).
- Modeled or measured ambient environmental (water) concentrations.

Details: Step 2, Calculating Chemical Risk

Cancer Risk

For chemicals classified as carcinogens, upper bound excess lifetime cancer risk, expressed as a unitless probability, is typically estimated by the linear low-dose cancer risk equation, where:

$$\text{cancer risk} = \text{LADD} \times q_1^*$$

For example:

for an LADD of 0.3 mg/kg-day and a q_1* of 0.02 $(\text{mg/kg-day})^{-1}$:

$$\text{cancer risk} = (0.3) \times (0.02) = 0.006$$

This cancer risk (on an individual basis) would mean a 6 in 1,000 risk of developing cancer from exposure to this particular chemical, in addition to baseline cancer risk.

Alternatively, cancer risk can be calculated by the lifetime average exposure level (in air or water) x unit risk factor (this is a variant of the linear low-dose equation).

For example:

for a lifetime average exposure level of 0.4 $\mu g/m^3$ and a unit risk of 0.0002 $(\mu g/m^3)^{-1}$:

$$\text{cancer risk} = (0.4) \times (0.0002) = 0.00008 \text{ (or } 8 \times 10^{-5}\text{)}$$

For higher doses (cancer risks above approximately 0.01), this linear equation is not considered valid. In this case the results should state "risks are above 0.01 but cannot be estimated more exactly." Cancer risk numbers are typically presented to one significant figure.

Noncancer Risk

For chemicals that exhibit noncancer toxicity, an HQ is calculated by:

$$HQ = PDR / RfD$$

For example:

for a PDR of 0.4 mg/kg-day and an RfD of 0.05 mg/kg-day:

$$HQ = (0.4) / (0.05) = 8$$

Chemicals that exhibit developmental toxicity are evaluated separately, using an RfD for developmental effects (RfD_{DT}). Short-term exposure can be of concern for developmental effects (because of the window of fetal vulnerability) so a peak exposure is used rather than a PDR for the entire duration of exposure:

$$HQ_{DT} = \text{peak exposure} / RfD_{DT}$$

Alternatively, if an RfC (typically for air) or RfC for developmental effects (RfC_{DT}) and corresponding exposure level is available, the HQ can be calculated by:

$$HQ = \text{lifetime average exposure level} / RfC$$

or:

$$HQ_{DT} = \text{peak exposure level} / RfC_{DT}$$

HQs (non-developmental) are typically calculated for long-term (chronic) exposure periods. They can also be calculated for subchronic or acute (shorter-term) exposure periods if subchronic or acute RfD (or RfC) and dose rates (or exposure levels) are determined in the Human Health Hazards Summary and Exposure Assessment modules. It is important to keep the exposure durations consistent; for example, subchronic RfDs combined with subchronic dose rates.

The HQ is based on the assumption that there is a level of exposure (i.e., the RfD) below which it is unlikely, even for sensitive subgroups, to experience adverse health effects. Unlike cancer risk, the HQ does not express *probability* (only the ratio of the estimated dose to the RfD or RfC) and it is not linear; i.e., an HQ of 10 does not mean that adverse health effects are 10 times more likely to occur than for an HQ of 1.

For chemicals where an RfD or RfC is not available, MOE is calculated by:

$$MOE = NOAEL / PDR \quad \text{or} \quad LOAEL / PDR$$

Alternatively, MOE can be calculated with an exposure level rather than a dose rate:

$$MOE = NOAEL \text{ or } LOAEL \,/\, \text{lifetime average exposure level}$$

As with the HQ, the MOE is not a probabilistic statement of risk. Very high MOE values, such as values greater than 100 for a NOAEL-based MOE or 1,000 for a LOAEL-based MOE, imply a very low level of concern. As the MOE decreases, the level of concern increases.

Details: Step 3, Calculating Pathway Risk for Multiple Chemicals

For pathways where exposure to more than one chemical is being assessed, the cancer risk results for each chemical are typically summed for each pathway:

$$\text{cancer risk}_{TOT} = \Sigma \text{ cancer risk for each chemical}$$

It should be noted that summing cancer risks assumes additivity of the chemical effects. Risks from exposures to more than one carcinogen are typically assumed to be additive, unless available information suggests otherwise.

The HQs can also be summed to calculate an HI:

$$HI = \Sigma \text{ HQ for each chemical}$$

Alternatively, HI can be calculated by:

$$HI = PDR_1/RfD_1 + PDR_2/RfD_2 + ... + PDR_i/RfD_i$$

Calculation of an HI also assumes additivity of the chemical effects. This is valid only where the chemicals elicit the same effect by the same mechanism of action. Typically, if an HI exceeds unity, the chemicals are segregated by effect and mechanism and segregated HIs recalculated. This segregation by mechanism of action and type of effect is not a simple exercise and should only be performed by an experienced toxicologist.

Details: Step 4, Summing Pathway Risks, if Applicable

In some situations, a receptor may be exposed to a chemical, or a mixture of chemicals, through more than one pathway (for example, a worker may be inhaling volatile chemicals from a solution and at the same time be exposed through the skin). In this case the total risk is equal to the risks from all relevant pathways. Cancer risks can be summed across pathways, where:

$$\text{total exposure cancer risk} = \text{cancer risk (pathway}_1\text{)} + \text{cancer risk (pathway}_2\text{)} + ... \text{ cancer risk (pathway}_i\text{)}$$

HI should be summed separately for different exposure durations (e.g., chronic, subchronic, shorter term durations); an HI for multiple pathways and similar exposure durations can be calculated by:

$$\text{total exposure HI} = \text{HI (pathway}_1\text{)} + \text{HI (pathway}_2\text{)} + \ldots \text{HI (pathway}_i\text{)}$$

Results are typically presented for each pathway separately (Step 3) as well as combined across pathways.

Details: Step 5, Calculating Population Cancer Risk, if Applicable

Cancer risks may be characterized in terms of individual or population risk. Risk to a population is typically calculated by:

cancer risk = individual cancer risk x number in exposed population

Population risks may also be calculated separately for areas with different levels of exposure. Population data sources may include the number in the exposed population from the Exposure Assessment module, census data, or other demographic data or work place surveys.

Details: Step 6, Assessing Uncertainty and Variability

Because information for risk characterization comes from the Environmental Hazards Summary, Human Health Hazards Summary, and Exposure Assessment modules, an assessment of uncertainty should include those uncertainties in the hazard and exposure data. There is also the issue of compounded uncertainty; as uncertain data are combined in the assessment, uncertainties may be magnified in the process. EPA guidance (e.g., *Risk Assessment Guidance for Superfund* [EPA, 1989a]; "Guidelines for Exposure Assessment" [EPA, 1992a]) contains detailed descriptions of uncertainty assessment, and the reader is referred to these for further information.

Uncertainties in the hazard data could include:

- Uncertainties from use of quantitative structure-activity relationships (QSARs) for aquatic toxicity.
- Using dose-response data from high dose studies to predict effects that may occur at low levels.
- Using data from short-term studies to predict the effects of long-term exposures.
- Using dose-response data from laboratory animals to predict effects in humans.
- Using data from homogeneous populations of laboratory animals or healthy human populations to predict the effects on the general human population, with a wide range of sensitivities.
- Assuming 100 percent absorption of a dose when the actual absorption rate may be significantly lower.
- Using toxicological potency factors from studies with a different route of exposure than the one under evaluation.

- Effects of chemical mixtures (effects may be independent, additive, synergistic or antagonistic).
- Possible effects of substances not included because of a lack of toxicity data.
- Carcinogen weight-of-evidence classifications; for any chemicals assessed as carcinogens (described in the Human Health Hazards Summary module), the weight-of-evidence classification should be presented with any cancer risk results.

Uncertainties in the exposure data could include:

- Description of exposure setting - how well the typical facility used in the exposure assessment represents the facilities included in the CTSA; the likelihood of the exposure pathways actually occurring.
- Possible effect of any chemicals that may not have been included because they are minor or proprietary ingredients in a formulation.
- Chemical fate and transport model applicability and assumptions - how well the models and assumptions that are required for fate and transport modeling represent the situation being assessed and the extent to which the models have been verified or validated.
- Parameter value uncertainty, including measurement error, sampling error, parameter variability, and professional judgment.
- Uncertainty in combining pathways for an individual.

In the CTSA, uncertainty is typically addressed qualitatively. Variability in the exposure assessment is typically addressed through the use of "exposure descriptors," which are discussed in the Exposure Assessment module.

Details: Step 7, Summarizing and Presenting Results

The risk characterization results are typically presented in tables, with the cancer risk, HQ and/or HI, and MOE calculated for each chemical. The results are also explained and summarized in the text along with the tables. The actual format of the tables can vary greatly, depending on the complexity of the analysis (the number of chemicals, scenarios, and pathways being assessed). A typical format is shown in Table 6-10.

TABLE 6-10: TYPICAL FORMAT FOR RISK CHARACTERIZATION RESULTS

(e.g., Dermal Contact with Solution X in Occupational Setting Performing Task Y)

Chemical	Cancer Risk [weight-of-evidence classification]	HQ	MOE
chemical *a* . . . **chemical *z***	result for *a* [B2] . . . result for *z* [B1]	result for *a* . . . result for *z*	result for *a* . . . result for *z*
sum of cancer risk, or HI, for pathway:	sum of cancer risks	sum of HQs (when appropriate)	(not summed)

Details: Step 8, Comparing CC to Aquatic Concentrations

Exposure concentrations below the CC are assumed to present low risk to aquatic species. Exposures that exceed the Cc indicate a potential for adverse impact on aquatic species. The level of concern increases as the ratio of exposure concentration to CC increases.

An ecological risk indicator may be calculated as a unitless ratio, for example:

> With a daily stream concentration of 2 mg/l and a CC of 1 mg/l, the ecological risk indicator = (2) / (1) = 2

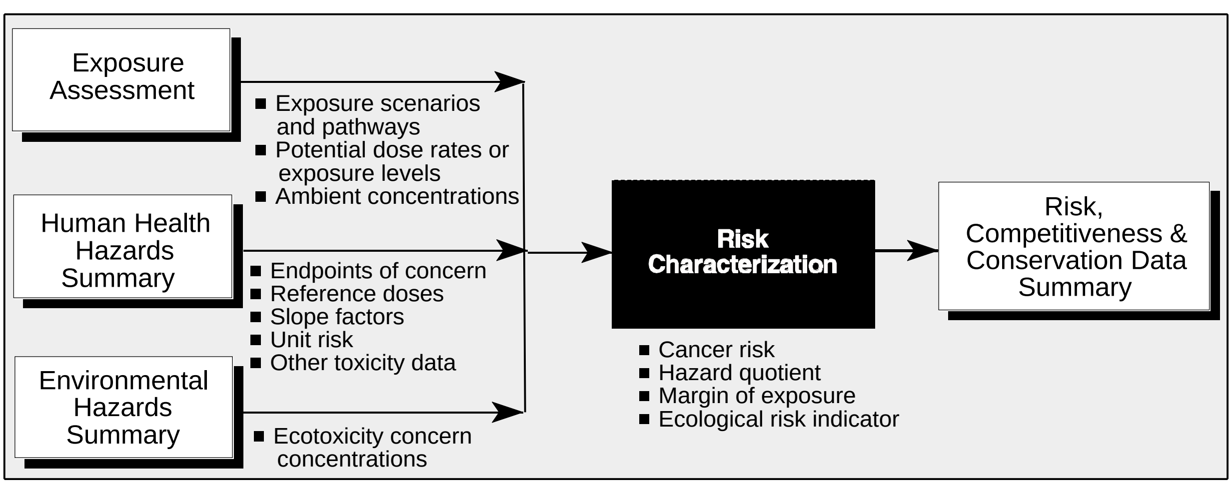
An ecological risk indicator greater than 1 indicates that the estimated or measured chemical concentration exceeds the concentration of concern for the aquatic environment based on chemical toxicity to aquatic organisms. The greater the number of days the CC is exceeded, the greater the potential risk.

Details: Step 9, Expressing Risk on a "Per Unit of Production" Basis

Where possible, also express risk characterization results on a "per unit of production" basis using an amount that is produced during the corresponding exposure period. For example, cancer risk can be expressed as risk/amount produced. This information will facilitate evaluating tradeoffs among alternatives in the Social Benefits/Costs Assessment and Risk, Competitiveness & Conservation Data Summary modules.

FLOW OF INFORMATION: The Risk Characterization module receives information from the Exposure Assessment, Human Health Hazards Summary, and Environmental Hazards Summary modules and transfers information to the Risk, Competitiveness & Conservation Data Summary module. Examples of information flows are shown in Figure 6-5.

FIGURE 6-5: RISK CHARACTERIZATION MODULE: EXAMPLE INFORMATION FLOWS



ANALYTICAL MODELS: None cited.

PUBLISHED GUIDANCE: Table 6-11 presents references for published guidance on risk characterization.

TABLE 6-11: PUBLISHED GUIDANCE ON RISK CHARACTERIZATION

Reference	Type of Guidance
Barnes, D.G. and M. Dourson. 1988. "Reference Dose (RfD): Description and Uses in Health Risk Assessments."	EPA's principal approach to assessing risk for health effects, other than cancer and gene mutations, from chronic chemical exposure.
Habicht, F.H. II. 1992. *Guidance on Risk Characterization for Risk Managers and Risk Assessors.*	Guidance for managers and assessors on describing risk assessment results in EPA reports, presentations, and decision packages with respect to reliability and uncertainty of the results of risk characterization.
Nabholz, J.V. 1991. "Environmental Hazard and Risk Assessment Under the United States Toxic Substances Control Act."	Discussion of environmental risk assessment procedures (as practiced under TSCA).
Nabholz, J.V., et. al. 1993a. "Environmental Risk Assessment of New Chemicals Under the Toxic Substances Control Act (TSCA) Section Five."	Discussion of environmental risk assessment procedures (as practiced under TSCA).
U.S. Environmental Protection Agency. 1987b. *The Risk Assessment Guidelines of 1986.*	Guidance on risk assessment methods; includes *Guidelines for Mutagenicity Risk Assessment, Guidelines for Carcinogen Risk Assessment*, and *Guidelines for the Health Risk Assessment of Chemical Mixtures*, originally published in the September 24, 1986 *Federal Register*, FR 51(185).
U.S. Environmental Protection Agency. 1989a. *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A).*	Detailed guidance for developing health risk information at Superfund sites; may also be applicable to other assessments of hazardous wastes and hazardous materials.
U.S. Environmental Protection Agency. 1990a. *Exposure Factors Handbook.*	Data related to exposure frequency and duration, and other human physiological and activity parameters.
U.S. Environmental Protection Agency. 1991b. "Guidelines for Developmental Toxicity Risk Assessment."	Guidance on assessing developmental toxicity risks; a revision of the *Guidelines for the Health Risk Assessment of Suspect Developmental Toxicants*, FR 51(185), September 24, 1986.

TABLE 6-11: PUBLISHED GUIDANCE ON RISK CHARACTERIZATION	
Reference	**Type of Guidance**
U.S. Environmental Protection Agency. 1991f. *Human Health Evaluation Manual, Supplemental Guidance:* "Standard Default Exposure Factors."	Exposure factors guidance to be used in the Superfund remedial investigation/feasibility study process.
U.S. Environmental Protection Agency. 1992a. "Guidelines for Exposure Assessment."	EPA guidance on exposure assessment; assessing uncertainty and variability in exposure data.
U.S. Environmental Protection Agency. 1994i. *Guidelines for Reproductive Toxicity Assessment.*	Guidance on assessing reproductive toxicity risks.
U.S. Environmental Protection Agency. 1994j. *Pesticide Occupational and Residential Cancer Risk Policy Statement*.	EPA's risk management policy with regard to occupational and residential (not dietary) cancer risks resulting from the use of pesticides. (Reflects Assistant Administrator's policy direction on risk which may be applicable to OPPT programs.)
U.S. Environmental Protection Agency. 1994k. "Final Report: Principles of Neurotoxicity Risk Assessment."	Guidance on assessing neurotoxic risks.
U.S. Environmental Protection Agency. 1994l. *OPPT Risk Assessment SOPs.*	A collection of guidance documents on various EPA exposure and risk characterization procedures.
U.S. Environmental Protection Agency. 1996b. "Proposed Guidelines for Carcinogen Risk Assessment."	Guidance on assessing carcinogenic risks; a revision of the *Guidelines for Carcinogen Risk Assessment,* FR 51(185), September 24, 1986.
Zeeman, M.G. 1995a. "EPA's Framework for Ecological Effects Assessment."	Provides an overview of the process used in the environmental toxicity assessment of chemicals
Zeeman, M.G. 1995b. "Ecotoxicity Testing and Estimation Methods Developed under Section 5 of the Toxic Substances Control Act (TSCA)."	Describes the developoment, validation, and application of SARs in the EPA OPPT.

Note: References are listed in shortened format, with complete references given in the reference list following Chapter 10.

DATA SOURCES: Hazard and exposure data are provided by the Human Health Hazards Summary, Environmental Hazards Summary, and Exposure Assessment modules.